UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

CAROL LEWIS
25 Old Harbor Rd.
Chatham, MA 02633

Plaintiff,

v. Case No. 15-13530

SYLVIA BURWELL in her official capacity
as Secretary, United States Department
of Health and Human Services,
615-F Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201,

Defendant.

COMPLAINT

Plaintiff, Carol Lewis, by her undersigned counsel, brings this action for judicial review of final agency decisions of Defendant Sylvia Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services, and states as follows:

PRELIMINARY STATEMENT

1. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§1395 *et seq.* ("the Medicare Act"), and the Administrative Procedure Act ("APA"), 5 U.S.C. §§551 *et seq.* Plaintiff, Carol Lewis, seeks judicial review of a final decision of Defendant, the Secretary ("the Secretary") of the Department of Health and Human Services ("HHS"), denying Medicare payment for claims relating to a continuous glucose monitor.

2. Ms. Lewis has had Type I diabetes for over 30 years, which despite being consistently conscientious in following nutritional instructions, regularly exercising, performing frequent self-monitoring (6 or more times daily), and following a comprehensive insulin administration regimen for her diabetes, her glucose levels still remain uncontrolled, i.e., "brittle."

3. Continuous glucose monitoring is the standard of care for brittle diabetics.

4. Ms. Lewis was prescribed a continuous glucose monitoring device ("CGM") before she became eligible for Medicare.

5. Because CGM is the standard of care and is recognized as durable medical equipment, Ms. Lewis' commercial insurance company covered it for at least five years.

6. A National Coverage Determination ("NCD") is a determination regarding coverage that exists nationally. NCD 40.2 provides Medicare coverage for home blood glucose monitors for diabetics who are Medicare beneficiaries.

7. In 2008, National Health Insurance Corporation ("NHIC") issued a local coverage determination ("LCD") L11530, indicating that blood glucose monitors and related accessories and supplies, would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient's physician states the patient is capable of using the device; and (3) the device is designed for home use rather than clinical use.

8. The NHIC LCD did not indicate that the CGM was not covered.

9. However, NHIC issued an informal communication known as an "Article" stating that NHIC considers CGM to be "precautionary."

10. The denial at issue in this action first arose when NHIC denied claims for Ms. Lewis' supplies for her CGM.

11. Ms. Lewis appealed these denials through the multi-step Medicare Part B appeals process, ultimately filing an appeal with the Medicare Appeals Council ("AC") on March 24, 2014.

12. Although the statute and Medicare regulations provide that the AC should render a decision within 90 days of a request for review, the case languished at the AC for over 18 months, the AC did not render a decision until September 25, 2015.

13. The exhaustion of the Medicare appeals process took over two years and has resulted in an inconsistent and unsupported decision by the AC, which is the Secretary's final decision for purposes of judicial review.

14. Plaintiff seeks an order reversing these coverage denials and instructing the Secretary to pay the claims at issue in accordance with applicable law. The decision at issue is arbitrary and capricious, not supported by the evidence or Medicare law, regulation or guidance, and is inconsistent with the medical records and the medical standard of care.

Jurisdiction and Venue

15. The Court has subject matter jurisdiction under 42 U.S.C. §§405(g) and 1395ff(b) (appeal of final Medicare program agency decision) and under 28 U.S.C. §§1331 (federal question) and 1361 (mandamus).

16. Venue lies in this judicial district under 42 U.S.C. §§405(g) and 1395ff(b) and 28 U.S.C. §1391(e).

Parties

17. Carol Lewis is a Medicare beneficiary residing at 25 Old Harbor Road, Chatham, MA 02633 who is seeking Medicare coverage of her claims for a CGM device and related accessories and supplies.

18. Ms. Lewis has been a Medicare beneficiary since at least January 1, 2013.

19. Plaintiff brings this action, which is an appeal of the Secretary's final decision denying Medicare claims for CGM supplies.

20. Defendant Sylvia Burwell is the Secretary of HHS, the federal department which contains the Centers for Medicare & Medicaid Services ("CMS"). The Secretary, the federal official responsible for administering the Medicare Program, has delegated that responsibility to CMS.

Factual Background

A. General Background of the Medicare Program

21. The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals afflicted with end-stage renal disease. *See* 42 U.S.C. §§1395 -1395ccc; 42 C.F.R. Parts 400 – 1004. Medicare includes Parts A through D. This action arises under Part B (covering basic non-hospital medical needs).

22. Under 42 U.S.C. §1395hh(a)(1), the Secretary is required to "prescribe such regulations as may be necessary to carry out the administration" of the Medicare program. That statute also states:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1). U.S.C. §1395hh(a)(2).

23. The Secretary has elected to publish many rules implementing the Medicare program in various manuals, such as the Medicare Program Integrity Manual ("MPIM") and the Medicare Claims Processing Manual ("MCPM"). However, under 42 U.S.C. §1395hh(a)(2), these manual provisions, which are not promulgated in accordance with the notice and comment

provisions of the APA, are not effective to the extent that any of them "establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" under Medicare.

B. Medicare Coverage and Payment of DMEPOS

24. Medicare Part B provides for coverage and payment for "medical and other health services," which includes durable medical equipment prosthetics, orthotics and supplies ("DMEPOS") provided to Medicare beneficiaries. *See* 42 U.S.C. §§1395k(a) and 1395x(n) and (s). To be paid by Medicare, medical devices and supplies must be found to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See* 42 U.S.C. §1395y(a).

25. Durable medical equipment ("DME") is defined at 42 C.F.R. §414.202. DME (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) generally not useful to an individual in the absence of an illness or injury; and (4) appropriate for home use.

26. The MCPM, Ch. 15, § 110.1(B)(2) reiterates these requirements.

27. DMEPOS is categorized by CMS pursuant to the Healthcare Common Procedure Coding System ("HCPCS") and is assigned an alpha-numeric code consisting of a letter and a four-digit number. Some items of DMEPOS are assigned a unique HCPCS code. To obtain a unique code, a medical device or supply must achieve sufficient volume, *i.e.*, adoption within the medical community. *See* www.cms.hhs.gov/MedHCPCSGcnInfo/Downloads/decisiontree.pdf.

28. If Medicare covers a piece of DME, it also covers the supplies necessary for the effective use of the DME.

29. Claims for Medicare payment for DMEPOS items supplied to Medicare beneficiaries are presented to DME Medicare Administrative Contractors ("DMACs"). DMACs adjudicate these claims as agents of the Secretary pursuant to contracts with him. The country is divided into four geographic jurisdictions, each of which has its own DMAC. A DMEPOS supplier must submit each of its claims to the DMAC having jurisdiction for reimbursement of that claim. *See* 42 C.F.R. §424.32.

30. After a claim has been submitted to the appropriate DMAC, the DMAC must determine if the item is covered or otherwise reimbursable under the Medicare Act. *See* 42 C.F.R. §405.920.

C. Medicare Coverage and Glucose Monitoring

31. A National Coverage Determination ("NCD") is "a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." *See* 42 C.F.R. §405.1060(a)(1).

32. An NCD is binding on all Medicare contractors, including administrative law judges ("ALJs") and the AC. *See* 42 C.F.R. §405.1060(a)(4).

33. To ensure coverage of diabetic testing equipment and supplies, in 2006, the Secretary issued the current effective version of the NCD providing Medicare coverage for blood glucose monitors. See Medicare National Coverage Determinations Manual §40.2, Home Blood Glucose Monitors (hereinafter "NCD 40.2").

34. Under NCD 40.2, a home blood glucose monitor is covered when:

a. The patient has been diagnosed as having diabetes;

b. The patient's physician states that that the patient is capable of being trained to use the particular device prescribed in an appropriate manner; and

c. The device is designed for home rather than clinical use. Id.

35. The NCD does not distinguish between single use home glucose monitors or continuous use glucose monitors.

36. In addition to an NCD, MACs, including DMACs, can issue local coverage determinations ("LCDs").

37. LCDs are issued after consideration of the peer-reviewed literature, consultation with the relevant medical community, notice and comment. See Medicare Program Integrity Manual ("MPIM") Ch. 13, §13.7.

38. When the ALJ is rendering a decision, although not bound by an LCD, an ALJ must give deference to an LCD. *See* 42 C.F.R. §405.1062. If an ALJ does not give deference to an LCD, the ALJ must explain why he or she did not.

39. In 2008, National Government Services ("NHIC") issued LCD L11530 indicating that blood glucose monitors and related accessories and supplies, would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient's physician states the patient is capable of using the device; and (3) the device is designed for home use rather than clinical use.

40. The NHIC LCD did and does not indicate that a CGM was and is not a Medicare covered benefit.

41. Articles are informal communications issued by MACs and may be issued without consultation with the relevant medical community or the peer reviewed literature. Articles are not subject to challenge by providers or beneficiaries, and are not entitled to any deference by either the QIC or ALJ. *See* 42 C.F.R. §405.1062.

42. Congress has made clear that enabling diabetic Medicare beneficiaries to manage and control their condition can reduce the complications from the disease and costs (e.g. hospital and emergency room visits) to the Medicare program.

D. The Process for Appeals of Medicare Claims Decisions

43. Congress has established a five-step process for a Medicare beneficiary, such as Ms. Lewis, to follow to obtain judicial review when she is dissatisfied with the initial determination of a claim by the DMAC.

44. Congress established this process to reduce the 368-day waiting time that appellants had experienced when Medicare claims denials were heard by the Social Security Administration.

45. The first step in the process is request for redetermination by the DMAC. *See* 42 C.F.R. §§405.940 through 405.958.

46. Upon a request for redetermination, the DMAC is required to adjudicate a claim and render a decision based on the evidence in the record. *See* 42 C.F.R. §405.954. Under 42 C.F.R. §405.956(b), the redetermination notice issued by the DMAC must include, *inter alia*, a summary of the evidence used in making the redetermination; an explanation of relevant laws, regulations, coverage rules, CMS policies that apply to the case; and a summary of the rationale for the redetermination in clear, understandable language. *See* 42 C.F.R. §405.956(b).

47. A Medicare beneficiary who is dissatisfied with a DMAC's redetermination decision may request reconsideration by the DME qualified independent contractor ("QIC"). *See* 42 C.F.R. §405.960. The QIC is required to review the record of the claims and issue a reconsideration decision having the same decision elements as the DMAC's redetermination decision. *See* 42 C.F.R. §405.976(b).

48. A Medicare beneficiary may appeal the QIC reconsideration decision by requesting a hearing before an Administrative Law Judge ("ALJ"). *See* 42 C.F.R. §405.1000.

49. ALJs are bound to follow an NCD. *See* 42 C.F.R. §405.1060(a)(4).

50. In contrast to an NCD, local coverage determinations ("LCDs") issued by MACs, including DMACs, are not binding on an ALJ. *See* 42 C.F.R. §405.1062(a).

51. When the ALJ is rendering a decision, although not bound by an LCD, if an ALJ applies an LCD, the ALJ must apply the LCD in place on the date the item or service was provided. *See* 42 C.F.R. §405.1034.

52. Articles, which are informal communications issued by MACs, may be issued without consultation with the relevant medical community. Articles are not subject to challenge by providers or beneficiaries, and are not entitled to any deference by either the QIC or ALJ. *See* 42 C.F.R. §405.1062.

53. Pursuant to the statute and Medicare regulations, an ALJ should render a decision within 90 days of a request for an ALJ hearing. 42 U.S.C. §1395ff(d)(1)(a); 42 .C.F.R §405.1016(a).

54. If an ALJ issues an unfavorable decision, a Medicare beneficiary may appeal the decision to the AC.

55. An NCD is binding on the AC and the AC limits its review to the evidence contained in the record before the ALJ. *See* 42 C.F.R §405.1122(a)(1).

56. Pursuant to the statute and Medicare regulations, the AC should render a decision within 90 days of a request for AC review. *See* 42 U.S.C. §1395(d)(2)(a); 42 C.F.R. §405.1100(c).

57. If the AC does not render a timely decision, a Medicare beneficiary can seek "escalation" to district court. *See* 42 C.F.R. §405.1132(a).

58. Pursuant to Medicare regulations, the AC must act within five days of receipt of a request for escalation, either rendering a decision or acknowledging it cannot so that a beneficiary can file a Federal action. *See* 42 C.F.R. §405.1132(a).

59. The AC's decision becomes the Secretary's decision and is the final agency decision for purposes of judicial review. *See* 42 C.F.R. §405.1136(d).

60. A Medicare beneficiary seeking judicial review of the Secretary's final decision may file a complaint "in the district court of the United States for the judicial district in which the party resides or where such individual, institution, or agency has its principal place of business." *See* 42 C.F.R. §405.1136; *see also* 42 U.S.C. §§405(g) and 1395ff(b). Timely judicial review is being sought for a decision rendered by the Secretary. *See* 42 C.F.R. §405.1130 and §405.1134.

E. The Process for Challenging an LCD

61. Medicare regulations also provide a mechanism for a Medicare beneficiary to file a challenge against an LCD. *See* 42 C.F.R. §426.400 et seq.

62. The LCD challenge process is independent from the claims appeal process and is conducted by an ALJ who is a member of the Civil Remedies Division of the Departmental Appeals Board of the Department of Health and Human Services (the "Board"). *See* 42 C.F.R. §426.310.

63. When a Medicare beneficiary files an LCD challenge, the relevant MAC is required to produce any information that the MAC considered when drafting an LCD including,

scientific articles, technology assessments, clinical guideless and statements from clinical experts (the "LCD Record"). *See* 42 C.F.R. §426.418.

64. The ALJ reviews the evidence submitted by the MAC and applying the reasonableness standard, determines whether the LCD Record is complete and adequate to support the validity of the LCD. *See* 42 C.F.R. §426.425(c).

65. If the ALJ determines the LCD is not valid under the reasonableness standards, the MAC must provide individual consideration for the claim that gave rise to the LCD challenge, and all subsequent claims for the same device or service, without using the LCD or LCD provisions found to be invalid. *See* 42 C.F.R. 426.460(b)(1).

STATEMENT OF FACTS AND PRIOR PROCEEDINGS

A. Continuous Glucose Monitoring and Brittle Diabetics

66. Unfortunately, despite consistently and conscientiously following nutritional instructions, regularly exercising, performing frequent self-monitoring (six or more times daily), and following a comprehensive insulin administration regimen for their diabetes, some individuals still have uncontrolled glucose levels. Such diabetics are known as "brittle diabetics."

67. Such individuals suffer from hypoglycemic unawareness, i.e., they are unaware of an impending, dangerous low drop in blood glucose. Hypoglycemic unawareness may result in prolonged and profound exposure to hypoglycemia, resulting in seizure, loss of consciousness and brain damage.

68. Brittle diabetics often have frequent nighttime hypoglycemic episodes which causes a progressive loss of mental function.

69. CGM alerts brittle diabetics of both hypo- and hyperglycemic episodes which can occur at a frequency that would confound any attempt to manage through simple finger stick blood glucose checks.

70. CGM operates by measuring the interstitial fluid under the skin which, as the device name implies, continuously tracks with and reflects the glucose concentration in the blood.

71. CGM is a physician-prescribed, FDA-approved medical device.

72. CGM is used solely by individuals with diabetes to aid in the treatment of their disease.

73. CGM has been recognized as the standard of care for brittle diabetics nationally and internationally.

74. Medical consensus statements/guidelines reflecting CGM as the standard of care for brittle diabetics have been issued by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring (which has recommended CGM since at least 2007); the American Diabetes Association (which has included the CGM in its recommendation since at least 2009); the Endocrine Society; the German Diabetes Association (which reviews the favorable consensus statements of many European nations); various French Endocrinology and Diabetic Societies; the European Society for Pediatric Endocrinology, the Pediatric Endocrine Society and the International Society for Pediatric and Adolescent Diabetes.

75. The American Medical Association passed a resolution in support of CGM coverage for Medicare beneficiaries.

76. The consensus of medical opinion regarding the safety and effectiveness of CGM for brittle diabetics is supported by at least nine peer-reviewed publications reflecting randomized, controlled clinical trials.

77. Based on the consensus statements, peer-reviewed literature and widespread acceptance of CGM for brittle diabetics, more than 95% of commercial insurers cover CGM.

78. An independent federally-funded technology assessment found CGM reasonable and medically necessary for brittle diabetics. See the Agency for Health Care Research and Quality ("AHRQ") report of 2010 (AHRQ at 102-103, 105).

B. <u>The Proceedings Below Relating to the Claims at Issue in this Action</u>

79. This is an action for judicial review of the final administrative decision of the Secretary with the AC Appeal Number 1-1727714901, M-14-1822 (issued September 25, 2015).

80. Ms. Lewis has had Type 1 diabetes for 30 years.

81. Despite frequent testing, she was unable to gain control of her diabetes. She also suffers from hypoglycemia and hypoglycemic unawareness.

82. Accordingly, her healthcare provider prescribed her a continuous glucose monitor which checks Ms. Lewis's glucose approximately 288 times a day and alerts her when she is experiencing a hypoglycemic event.

83. Ms. Lewis's healthcare provider testified that CGM was and is reasonable and medically necessary for Ms. Lewis.

84. With CGM, Ms. Lewis had a "vast" clinical improvement of her blood glucose level control.

85. Ms. Lewis filed a claim for the CGM and related supplies which were denied by NHIC.

86. Ms. Lewis appealed the denial through the Medicare administrative appeal process.

87. On July 7, 2013, Ms. Lewis filed a request for an ALJ hearing.

88. An ALJ hearing was conducted on October 30, 2013 before ALJ Zatopa.

89. During the October hearing, Ms. Lewis's healthcare provider, Dr. Richard Beaser, testified that CGM was not precautionary but was medically necessary and essential for Ms. Lewis.

90. Dr. Beaser explained that Ms. Lewis' medical need for CGM is extreme.

91. Dr. Beaser noted that CGM prevents hypoglycemic and hyperglycemic events and premature death.

92. Although Medicare ALJs may retain a clinical and scientific expert to facilitate their understanding of the case, the ALJ did not retain such an expert in this case.

93. Although the statute and Medicare regulations provide that a decision should be rendered in 90 days, it was not until February 6, 2014, that ALJ Zatopa rendered an unfavorable decision finding that CGM is not covered by Medicare, 214 days after Ms. Lewis' request, far in excess of the statutory time period.

94. On March 21, 2014, within the prescribed statutory time period, Ms. Lewis appealed the unfavorable ALJ decision to the AC.

95. Within the statutory time period, on December 2014, Ms. Lewis also filed a challenge to the provision in the NHIC Article that asserted CGM was precautionary.

96. In response to the challenge, NHIC did not produce a single article or the opinion of a single medical expert in support of its assertion that CGM was precautionary.

97. On September 11, 2015, Judge Sickendick of the DAB Civil Remedies Division found that under a reasonableness analysis, the Article provision asserting that CGM was precautionary was not supported by the LCD Record.

98. Judge Sickendick also found that CGM met the statutory definition of DME.

99. On September 14, 2015, after her case had been pending at the AC for more than a year, i.e., long after the 90 day period prescribed by Medicare regulations, Ms. Lewis filed a request for escalation to Federal district court.

100. Although the statute and Medicare regulations require the AC to act within five days of a request for escalation to district court, and the AC has repeatedly publicly acknowledged its obligation, the AC took none of the required actions. *See* 42 U.S.C. 1395ff(d)(2)(A); 42 C.F.R. §405.1132.

101. On September 25, 2015, after her case had been pending at the AC for more than 550 days, the AC affirmed the ALJ's denial of Medicare coverage of CGM although it modified the basis of denial.

102. Without support, and ignoring Judge Sickendick's explicit findings, the AC found that the CGM is simply precautionary, does not serve a medical function, and therefore is not covered under the DME Medicare benefit.

103. The Secretary has failed one her most vulnerable populations, Medicare beneficiaries, by rendering decisions that clearly violate the statutory and regulatory timelines; are contrary to the overwhelming medical and scientific evidence; and are contrary to her own determinations in regarding the evidence supporting CGM.

104. The Secretary's delays in resolving this issue and failing to consider the overwhelming evidence, have place Ms. Lewis, and other similarly situated Medicare beneficiaries, in a precarious medical state.

COUNT I
Violation of APA under 5 U.S.C. §706
(CGM is Not Precautionary and Not Excluded from Coverage)

105. Plaintiff hereby incorporates by reference paragraphs 1 to 104 herein.

106. Under the Medicare statute, 42 U.S.C. §1395ff(b), the final agency decision included in this action is subject to judicial review under the applicable provisions of the APA. Under the APA, the reviewing court shall set aside the final agency decision if, *inter alia,* it is contrary to law, arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence in the record.

107. To the extent that the Secretary's decision in this action found that CGM is precautionary and therefore not reasonable and medically necessary, the Secretary's decision must be set aside because it is contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

108. CGM is reasonable and medically necessary for brittle diabetics as widely recognized.

109. Based on the foregoing, the Secretary's decision that the CGM is not covered because it is precautionary, is contrary to Medicare regulations, arbitrary and capricious, and unsupported by substantial evidence in the record, and Plaintiff asks the Court to reverse the Secretary's decisions and issue an order finding that the CGM is not precautionary and is reasonable and medically necessary, and direct the Secretary to make appropriate payment for the device.

COUNT II
Violation of APA under 5 U.S.C. §706
(CGM is Covered Under NCD 40.2)

110. Plaintiff hereby incorporates by reference paragraphs 1 to 109 herein.

111. The Secretary's decision in this action must be set aside because it is arbitrary, capricious, and unsupported by substantial evidence in the record. The finding that CGM is precautionary is not supported by the record and is contrary to the evidence which includes numerous peer-reviewed studies, professional society statements and practicing physicians and NCD 40.2.

112. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is reasonable and medically necessary under NCD 40.2.

COUNT III

Violation of APA under 5 U.S.C. §706
(Failure to Follow the NCD)

113. Plaintiff hereby incorporates by reference paragraphs 1 to 112 herein.

114. To the extent that the Secretary's decision is premised on its failure to apply the NCD 40.2, the Secretary's decision must be set aside because it is contrary to law, arbitrary and capricious and without observance of procedure required by law. 42 C.F.R. §405.1060(a)(4).

COUNT IV
Violation of APA under 5 U.S.C. §706
(CGM is Not Non-Covered Under LCD L27231)

115. Plaintiff hereby incorporates by reference paragraphs 1 to 114 herein.

116. The Secretary's decision in this action must be set aside because it is arbitrary, capricious, and unsupported by substantial evidence in the record. The finding that CGM is

precautionary is not supported by the record and is contrary to the evidence which includes numerous peer-reviewed studies, professional society statements and practicing physicians.

117. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is reasonable and medically necessary under LCD L11530.

COUNT V

Violation of APA under 5 U.S.C. §706 (Failure to Follow the LCD)

118. Plaintiff hereby incorporates by reference paragraphs 1 to 117 herein.

119. To the extent that the Secretary's decision is premised on its failure to apply the LCD L11530, the Secretary's decision must be set aside because it is contrary to law, arbitrary and capricious and without observance of procedure required by law. 42 C.F.R. §405.1060(a)(4).

120. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is reasonable and medically necessary under LCD L11530 and directing the Secretary to follow LCD L11530.

COUNT VI

Violation of APA under 5 U.S.C. §706 (Deference to the Article)

121. Plaintiff hereby incorporates by reference paragraphs 1 to 120 herein.

122. To the extent that the Secretary's decision is premised on giving deference to an NHIC Article, which is not an LCD and is not entitled to deference, the Secretary's decision must be set aside because it is contrary to law, regulation and arbitrary and capricious, and without observance of procedure required by law.

123. The Secretary provided no basis for refusing to give deference to the LCD, or acknowledging that even if the Article applied, it should not be given deference in view of Ms. Lewis's uncontested dire need for CGM to avoid life-endangering glucose swings.

124. The Secretary provided no basis for applying the Article which has been found not supported by sufficient clinical and scientific evidence.

COUNT VII

Violation of APA under 5 U.S.C. §706 (Failure to follow the Statutory Definition of DME)

125. Plaintiff hereby incorporates by reference paragraphs 1 to 124 herein.

126. To the extent that the Secretary's decision is premised on CGM not meeting the statutory definition of DME, the Secretary's decision must be set aside because it is contrary to law, regulation, her own manual provisions, is arbitrary and capricious, and without observance of procedure required by law.

127. The Secretary provided no basis for refusing to apply the statutory definition of DME as set forth in her manual provisions that further articulate her interpretation of the statutory provisions and is contrary to law and regulation and is arbitrary and capricious.

COUNT VIII

Relief Under the Mandamus Act 28 U.S.C. § 1361

128. Plaintiff hereby incorporates by reference paragraphs 1 to 127 herein.

129. The Mandamus Act, 28 U.S.C. §1361 vests district courts with original jurisdiction over any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to a plaintiff.

130. Under Federal law, HHS has a clear, non-discretionary duty to "conduct and conclude a hearing on a decision of a qualified independent contract . . . and render a decision on

such a hearing by not later than the end of the 90-day period beginning on the date a request for a hearing has been timely filed." 42 U.S.C. §1395ff(d)(1)(A).

131. Under Federal law, HHS has a clear, non-discretionary duty for the AC to render a decision within 90-days of a request for review. 42 U.S.C. §1395ff(d)(2)(A).

132. Absent Mandamus, Medicare beneficiaries such as Ms. Lewis have no adequate remedy.

Requested Relief

WHEREFORE, Plaintiff requests:

1. An order setting aside the Secretary's decision that CGM is not covered;
2. An order declaring CGM is eligible for Medicare coverage;
3. An order remanding this action to the Secretary with instruction to cover Ms. Lewis's CGM and related supplies;
4. An order that this Court will retain jurisdiction over the decisions at issue until the Secretary's payment of the claims at issue has been completed;
5. A declaratory judgment that the Secretary's delay in adjudicating Medicare appeals violates Federal law.
6. An order awarding legal fees and costs of suit incurred by Plaintiff; and
7. Such other relief as this Court may deem and consider appropriate.

Date: October 8, 2015

Respectfully submitted,

Attorneys for Plaintiff

By: Laurie J. Bejoian, Esq.

325B Great Road
Littleton, MA 01460
TEL 978-486-9145
FAX 978-486-9362
Email: ljblaw.ljbejoian@gmail.com
BBO# 545312

OF COUNSEL:
PARRISH LAW OFFICES
Debra M. Parrish
788 Washington Road
Pittsburgh, PA 15228
TEL 412-561-6250
FAX 412-561-6253
Email: debbie@dparrishlaw.com
Pro Hac Vice Admission in Process